

Pfizer-BioNTech COVID-19 Vaccine

EUA 27034

**Response to 25 April 2021 CBER Information Request
Regarding the Emergency Use Authorization Request for
Individuals 12-15 Years of Age**

27 April 2021

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LIST OF ABBREVIATIONS

Abbreviation	Term
AE	adverse event
CBER	Center for Biologics Research and Evaluation
COVID-19	Coronavirus Disease 2019
EUA	Emergency Use Authorization
FDA	United States Food and Drug Administration
SAE	serious adverse event
SNP	safety narrative plan

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1. INTRODUCTION

Reference is made to the Emergency Use Authorization (EUA) 27034 Amendment submitted 09 April 2021 to extend the EUA of the Pfizer-BioNTech COVID-19 Vaccine to individuals 12 through 15 years of age.

The purpose of this document is to respond to CBER's comments communicated from Ramachandra Naik, PhD (CBER) to Neda Aghajani Memar (Pfizer Inc.) on 25 April 2021, requesting an additional table for participants 16-25 years of age and case narratives for certain participants 16-55 years of age.

CBER's comments are shown in ***bold italics*** and are followed by the Sponsor's responses in plain text below.

2. CBER COMMENTS

2.1. Comment 1

For the age group of participants 16-25 years of age, please provide the number of participants who contributed to the safety population (total and by treatment group) and percentage of participants with greater than or equal to 2 months, and greater than or equal to 1 month of blinded follow up after Dose 2. Please also present these data in table format similar to the 12-15 years age group, presented in Table 3, page 20 of the document m1.19 eua-amend-12-15-years.pdf.

Sponsor Response

As shown below in [Table 1](#), there were 3770 participants 16-25 years of age (1867 in the BNT162b2 and 1903 in the placebo groups) in the safety population. Of these 3622 (96.1%) had at least 1 month of blinded follow-up after the second dose of BNT162b2 and 3292 (87.3%) had at least 2 months of blinded follow-up after the second dose of BNT162b2.

Table 1. Follow-up Time After Dose 2 – Subjects 16 Through 25 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N ^a =1867) n ^b (%)	Placebo (N ^a =1903) n ^b (%)	Total (N ^a =3770) n ^b (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled follow-up period			
<1 Month	64 (3.4)	84 (4.4)	148 (3.9)
≥1 Month	1803 (96.6)	1819 (95.6)	3622 (96.1)
≥2 Months	1645 (88.1)	1647 (86.5)	3292 (87.3)
≥1 Month to <2 months	158 (8.5)	172 (9.0)	330 (8.8)
≥2 Months to <4 months	673 (36.0)	679 (35.7)	1352 (35.9)
≥4 Months to <6 months	763 (40.9)	791 (41.6)	1554 (41.2)
≥6 Months	209 (11.2)	177 (9.3)	386 (10.2)
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.			
Note: Follow-up time was calculated to the cutoff date or the date of unblinding, whichever date was earlier.			
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.			
b. n = Number of subjects with the specified characteristic.			
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 26APR2021 (09:55)			
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA_RR/adsl_fu_d2_ped_1655			

2.2. Comment 2

For participants 16-55 years of age (document c4591001-16-55-tables-2.pdf, page 9), please provide case narratives for 19 subjects reporting a life-threatening SAE (n=8 BNT162b2, n=11 placebo), 16 subjects who withdrew from the study due to an AE related to vaccination (n= 9 BNT162b2, n=7 placebo), and for 2 deaths in placebo participants. If any of the narratives were provided in the initial EUA (27034/0) and there is no updated information, please provide only the subject ID numbers.

Sponsor Response

The requested safety narratives for the 19 subjects reporting life threatening SAEs, 16 subjects who withdrew due to AEs related to vaccination, and 2 subjects in the placebo group who died are provided in [Module 5.3.5.1](#). The narratives were programmed according to the safety narrative plan (SNP) developed for the EUA and BLA, and therefore the reason in the narrative header for the requested life threatening SAEs matches the SNP. For the 3 categories requested above, please refer to the provided narrative table of contents to locate the appropriate narratives. Narratives that were previously provided have been updated since the EUA submission (eg, addition of Visit 3 for placebo participants enrolling in cross-over BNT162b2 administration) and are therefore included. Only 6 of the narratives included in this submission are new and have not been previously submitted:

- C4591001 1156 11561124
- C4591001 1141 11411153
- C4591001 1218 12181057
- C4591001 1251 12511239
- C4591001 1087 10871354
- C4591001 1125 11251243

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Final Approval

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